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| 09/833,229 | 04/11/2001 | Avram Scheiner | 279.337US1 | 2999 |

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| EXAMINER | |
|---|---|
| DROESCH, KRISTEN L | |
| **ART UNIT** | **PAPER NUMBER** |
| 3762 | 9 |

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/833,229 | SCHEINER ET AL. | |
| | Examiner | Art Unit | |
| | Kristen L Droesch | 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-22,56-65 and 73-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,56-65 and 73-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 April 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1-3, 8-11, 13-16, 19, 20-22, and 73-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Carlson et al. (5,792,195). Carlson et al. shows a first heart sound sensor, (34) a second cardiac electrical signal sensor (24), a third cardiac electrical signal sensor (26), an interface circuit (42) and a control circuit (32, 36, 38) that includes a bandpass filter (46), a systole detector, and an ensemble averager (96,98) (Fig. 2; Col. 6, lines 44 -55; Col. 7, lines 23-58).

Regarding claims 2-3, 10-11, and 21, Carlson et al. further shows the heart sound sensor is an accelerometer (34) located internal to the implantable housing (10)

With respect to claims 8, 19, Carlson et al. shows the data transmitted is processed data (Col. 4, lines 46-62).

Regarding claim 13, the second sensor includes an EGM sensing electrode (16,18,20,22) and the second signals are representative of EGM electrical signals.

With respect to claims 14-16, and 22, Carlson et al. shows the second sensor (24) includes an atrial sensing electrode (20, 22), and the third sensor (26) includes a ventricular sense electrode (16,18) wherein the second sensor is disposed in the right side of the heart.

Regarding claims 20 and 73, Carlson et al. shows a systole detector where detection of systole triggers the ensemble averager (Col. 6, line 40 –Col. 7, line 13).

With respect to claims 9 and 74, Carlson et al. shows a bandpass filter (46) coupled to the sensor (34, 44) and ensemble averager (96, 98) where the output of the band pass filer is applied to the ensemble averager (Figs. 3A-3C).

Regarding claim 75, Carlson et al. shows the control circuit (32, 36, 38) comprises a band pass filter (46) a rectifier (78), coupled to the band pass filter and a low pass filter (80) coupled to the rectifier and the ensemble averager (96, 98) (Figs. 3A-3C).

With respect to claims 76-77, Carlson et al. shows averaging includes sequentially averaging a number of completed cardiac cycle over a period of time when a patient condition is present (Col. 6, line 40 – Col. 7, line 54).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. in view of Lekholm (4,763,646). Although Carlson et al discloses the claimed invention except for the heart sound sensor being located externally from the implantable housing, attention is directed Lekholm who teaches that the heart sound detector can be located on a separate line or on an electrode lead. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the sensor as taught by Carlson et al. with the sensor of Lekholm, since applicant has not disclosed that this location of the sensor provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any location for the sensor such as the external location taught by Lekholm for detecting heart sounds.

5. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. in view of Sholder et al. (5,899,928). Although Carlson et al. discloses the claimed invention except for explicitly teaching the interface circuit is configured to communicate using radio frequency or optical signals, attention is directed to Sholder et al. who teaches it is well known to use RF and optical signals for communication between implantable devices and external devices. (Col. 8, lines 52-55). It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the interface circuit as taught by Carlson et al. with an interface circuit that communicates via RF or optical signals, since applicant has not disclosed that these particular communication means provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any means for communication such as the RF or optical signal communication taught by Sholder et al. for communication between an implantable device and an external device.

6. Claims 7, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. in view of Turcott (6,409,675). Although Carlson et al. discloses the claimed invention except for explicitly teaching the transmitted data includes raw data determined by digitizing the sensed signals, attention is directed to Turcott which shows raw data can be recorded by an implantable device and transmitted via telemetry to an external processor (Col. 14, lines 38-48). It would have been obvious to one with ordinary skill in the art at the time the invention was made to transmit raw data rather than processed data because it would be far simpler and the step of processing the data would be omitted. Omission of an element and its function if the function of the element is not desired is generally recognized as being within the level of ordinary skill in the art. In re Kuhle, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlson et al. in view of Tockman et al. (5,540,727). Although Carlson et al. discloses the claimed invention except for explicitly teaching the second sensor is located in a left side of a heart, attention is directed to Tockman who shows a similar device with a sensor (27, 29) located in the left side of the heart for sensing ventricular electrical signals (Col. 3, lines 20-28). It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to locate the second sensor in a left side of a heart, since applicant has not disclosed that this particular location provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any location for the second sensor such as the location in a left heart taught by Tockman et al. for sensing left ventricular electrical signals.

8. Claims 1-3, 8, 56-59, and 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daum (6,453,201) in view of Tockman et al. (5,540,727).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

With respect to claim 1, Daum et al. shows a first heart sound sensor, (50) a second cardiac electrical signal sensor (24), a third cardiac electrical signal sensor (34), an interface circuit (40) and a control circuit (10) (Fig.1). Although Daum et al. fails to show an ensemble averager, attention is directed to Tockman et al. which teaches utilizing and ensemble averager to ensemble average sensor signals in order to eliminate transient non-periodic noise (Col. 5, lines 49-55). Therefore it would have been obvious to one with ordinary skill in the art at the time the

invention was made to modify the device of Daum et al. with an ensemble averager as taught by Tockman et al. in order to eliminate transient non-periodic noise.

Regarding claims 2-3, Daum et al. further shows the heart sound sensor is an accelerometer (50) located internal to the implantable housing (10) (Col. 3, lines 4-8).

With respect to claim 8, Daum et al. shows the data transmitted is processed data (53).

Regarding claims 56-58, Daum et al. shows a method of outputting heart sounds using an implanted sensor comprising detecting heart sounds using a first implanted sensor, transmitting data representative of heart sounds to an external system, detecting first and second cardiac electrical signals using a second and third implanted sensor and transmitting data representative of the first and second cardiac electrical signals to the external system (Col. 3, lines 35-46). Although Daum et al fails to show generating data representative of heart sounds using ensemble averaging, attention is directed to Tockman et al. which teaches generating data representative of heart sounds using ensemble averaging in order to eliminate transient non-periodic noise (Col. 3, line 66-Col. 4, line 4, lines 49-55). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Daum et al. with generating data representative of heart sounds using ensemble averaging as Tockman et al. teaches in order to eliminate transient non-periodic noise.

With respect to 59, Daum et al. shows generating control signals using first data representative of heart sounds from the implanted system; applying control signals (trigger) to an output device (12) to generate outputs that are representative of the detected heart sounds. (Col. 2, lines 15-21, Col. 4, lines 1-8). Although Daum et al fails to show generating data representative of heart sounds using ensemble averaging, attention is directed to Tockman et al.

which teaches generating data representative of heart sounds using ensemble averaging in order to eliminate transient non-periodic noise (Col. 3, line 66-Col. 4, line 4, lines 49-55). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Daum et al. with generating data representative of heart sounds using ensemble averaging as Tockman et al. teaches in order to eliminate transient non-periodic noise.

Regarding claim 62, Daum et al. shows generating control signals (trigger) from second data representative of first cardiac electrical signals from the implanted system; applying control signals (trigger) to an output device (12) to generate outputs that are representative of the detected heart sounds. (Col. 3, lines 37-39, Col. 2, lines 15-21, Col. 4, lines 1-8)

With respect to claim 63, Daum et al. shows outputting relative timing information between the heart sounds and the first cardiac signals on the output device (12) (Col. 3, lines 38-40).

Regarding claim 64, Daum et al. shows generating control signals (trigger) from third data representative of second cardiac electrical signals from the implanted system; applying control signals (trigger) to an output device (12) to generate outputs that are representative of the detected heart sounds. (Col. 3, lines 37-39, Col. 2, lines 15-21, Col. 4, lines 1-8)

With respect to claim 65, Daum et al. shows outputting relative timing information between the heart sounds and the second cardiac signals on the output device (12) (Col. 3, lines 38-40).

9. Claims 9-11, 13-16, 17, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daum (6,453,201) in view of Tockman et al. (5,540,727) and further in view of Carlson et

al. (5,792,195). Daum et al. shows a first heart sound sensor, (50) a second cardiac electrical signal sensor (24), a third cardiac electrical signal sensor (34), an interface circuit (40) and a control circuit (10) (Fig.1). Although Daum et al. fails to show an ensemble averager, attention is directed to Tockman et al. which teaches utilizing and ensemble averager to ensemble average sensor signals in order to eliminate transient non-periodic noise (Col. 5, lines 49-55). Although Daum et al. and Tockman et al. fail to show a band pass filter, attention is directed to Carlson et al which teaches a band pass filter to minimize the amount of noise due to breathing, body motion, muscle twitch, etc. (Col. 4, line 65-Col. 5, line 9). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Daum et al. with an ensemble averager as taught by Tockman et al. in order to eliminate transient non-periodic noise and further modify the device of Daum et al. and Tockman et al. with a band pass filter in order to minimize the amount of noise due to breathing, body motion, muscle twitch, etc.

Regarding claims 10-11, Daum et al. further shows the heart sound sensor is an accelerometer (50) located internal to the implantable housing (10) (Col. 3, lines 4-8).

Regarding claim 13, Daum et al. shows the second sensor includes an EGM sensing electrode (24, 34) and the second signals are representative of EGM electrical signals. (Col. 2, lines 4-7, 54-66).

With respect to claims 14-16, Daum et al. shows the second sensor (34) includes an atrial sensing electrode, and the third sensor (24) includes a ventricular sense electrode, wherein the second sensor is disposed in the right side of the heart.

Regarding claim 17, Tockman et al. shows a sensor (27, 29) located in the left side of the heart for sensing ventricular electrical signals (Col. 3, lines 20-28).

With respect to claim 19, Daum et al. shows the data transmitted is processed data (53).

10. Claims 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott (6,409,675) in view of Tockman et al. (5,540,727).

With respect to claims 56 and 59, Turcott shows a method of outputting heart sounds using an implanted system including receiving first data representative of detected heart sounds (Col. 7, lines 37-40), applying control signals to an output device to cause the output device to generate outputs representative of the detected heart sounds (Col. 13, lines 60-65). Although Turcott fails to show generating data representative of heart sounds using ensemble averaging, attention is directed to Tockman et al., which teaches generating data representative of heart sounds using ensemble averaging in order to eliminate transient non-periodic noise (Col. 3, line 66-Col. 4, line 4, lines 49-55). Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Turcott. with generating data representative of heart sounds using ensemble averaging as Tockman et al. teaches in order to eliminate transient non-periodic noise.

With respect to claims 57-58, Turcott shows detecting first and second cardiac electrical signals using a second and third implanted sensor and transmitting data representative of the first and second cardiac electrical signals to the external system (Col. 15, lines 35-49).

11. Claims 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott (6,409,675) in view of Tockman et al. (5,540,727) as applied to claim 59 and further in view of (Bauman et al. (5,836,987). Turcott and Tockman et al. are as explained before. Although

Turcott and Tockman et al. show receiving ECG signals and generating control signals including using ECG data (Col. 15, lines 35-49), Turcott fails to show using a surface ECG. Bauman et al. shows a similar device for measuring heart sounds from an implantable system. Bauman et al. teaches that in conjunction with the implanted system either an internal or external (surface) electrogram can be used (Col. 2, lines 61-67). It would have been obvious to one with ordinary skill in the art at the time the invention was made to employ external (surface) ECG data for the ECG data of Turcott and Tockman et al. wherein so doing would amount to mere substitution of one functional equivalent for another that would work equally well on the Turcott and Tockman et al. device.

Regarding claim 61, Turcott further shows outputting relative timing information between the heart sounds and ECG events on the output device (Col. 16, line 10- Col. 17-line 13).

***Response to Arguments***

12. Applicant's arguments with respect to claim1-22, 56-59, and 62-65 have been considered but are moot in view of the new ground(s) of rejection.

13. Applicant's arguments filed 4/3/03 with respect to claims 60, and 61, have been fully considered but they are not persuasive.

14. Regarding claims 60-61, the examiner points out that an external electrocardiogram is a surface ECG, otherwise known as an external electrocardiogram measured with surface electrodes. The examiner is unaware of alternative means of measuring an external ECG, since good conductivity with the surface of the body is essential for measuring an external ECG.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., connecting a surface ECG to the microprocessor based controller enclosed in an implantable housing) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

As stated above, the motivation for making the combination of the references is that Baumann shows that using an external (surface) ECG is functionally equivalent to using an intracardiac (internal) ECG, therefore showing that it is within the level of ordinary skill in the art to use external (surface) ECG's and internal ECG's interchangeably. Turcott and Tockman et al. teach the method but for the exception of using an external (surface) ECG, while Baumann et al. teaches an implantable device that records heart sounds via an accelerometer and records ECG's via either an internal or external (surface) cardiac electrogram.

***Conclusion***

15: Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 8:00 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kristen Droesch

kld
May 19, 2003

KENNEDY SCHAETZLE
PRIMARY EXAMINER
5-19-03